MAY - 8 2012

510(K) SUMMARY

FOR

SOMATOM Definition Flash

Submitted by:

Siemens Medical Solutions USA, Inc.

51 Valley Stream Parkway

Malvern, PA 19355

Date Prepared: May 4, 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**

Mrs. Kimberly Mangum
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2. **Device Name and Classification**

Product Name:	SOMATOM Definition Flash
Propriety Trade Name:	SOMATOM Definition Flash
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	90JAK

3. Substantial Equivalence:

Siemens SOMATOM Definition Flash Computed Tomography X-ray systems, configured with software version SOMARIS/7 VA44 is substantially equivalent to the following medical device in commercial distribution:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens SOMATOM Definition Flash (with SOMARIS7/ VA40)	K082220	10/10/2008
Siemens SOMATOM Definition Flash (with Stellar Detector) (with SOMARIS7/ VA40)	K113342	12/29/2011

4. Device Description:

The Siemens SOMATOM Definition Flash is a Computed Tomography X- ray System, which features two continuously rotating tube-detector systems and functions according to the fan beam principle. The SOMATOM Definition Flash produces CT images in DICOM format, which can be used by post-processing applications commercially distributed by Siemens and other vendors.

The system software is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation. The new version of system software, SOMARIS/7 VA44, allows the reconstruction of images with a slice thickness of 0.5mm for SOMATOM Definition Flash systems equipped with Stellar Detector.

The computer system delivered with the CT scanner is able to run the post processing applications optionally. The Stellar Detector will be offered as an optional upgrade to the cleared SOMATOM Definition Flash CT systems.

5. Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:

The modified SOMATOM Definition Flash CT Systems configured with software version SOMARIS/7 VA44 will be marketed under the trade name SOMATOM Definiton Flash. The modifications introduced with software version SOMARIS/7 VA 44 are as follows:

- Within the Dual Energy Workflow it is now possible to automatically reconstruct dual energy combined images. Furthermore the 3D reconstruction will now

support dual energy image data.

- For systems using Stellar Detector (cleared in Premarket Notification K113342 on 12/29/2011) and SAFIRE (cleared in Premarket Notification K103424 on 11/22/2011) the new software provides a mode, which allows the reconstruction of 0.5mm slices without using UHR option Using a reconstruction of 0.5mm slices provides a z-axis resolution of 0.3mm.

The modified SOMATOM Definition Flash CT Systems configured with software version SOMARIS/7 VA44 as described in this premarket notification has similar intended use and fundamental scientific technical characteristics as the predicate devices.

6. **Nonclinical Testing:**

The modifications described in this premarket notification were supported with verification/validation testing as well as phantom tests to evaluate 0.5 mm slice width. Fourier sensitivity transformation of the slice sensitivity profiles with respect to the z-coordinate was assessed to determine the modulation transfer function for 0.5 mm slice thickness. Phantom testing was also performed to determine the detectable spatial frequency in the z-direction, and access the lines per centimeter with respect to the z-axis.

7. **Indications for Use:**

The Siemens SOMATOM Definition Flash system is intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

In addition the SOMATOM Definition Flash is able to produce additional image planes and analysis results by executing optional post processing features, which operate on DICOM images.

The images and results delivered by the system can be used by a trained physician as an aid in diagnosis.

(*spiral planes: the axial planes resulting from the continuous rotation of detectors and x- ray tube, and the simultaneous translation of the patient.)

8. **General Safety and Effectiveness Concerns**:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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Ms. Kimberly Mangum
Regulatory Affairs Specialist
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K121072
Trade/Device Name: SOMATOM Definition Flash
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: March 23, 2012
Received: April 9, 2012

Dear Ms. Mangum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K121072

Device Name: ***SOMATOM Definition Flash***

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In vitro Diagnostic Device (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

K121072